

REMARKS

In the Office Action issued July 2, 2003, all pending claims 1-9, 11-22, and 24-34 were rejected. In response thereto, claims 1, 21, 22 and 34 have been amended. Upon entry of this amendment, claims 1-9, 11-22 and 24-34 remain pending for the Examiner's consideration. Withdrawal of the previous double patenting rejection and the rejections under Section 112, first and second paragraphs, is acknowledged. Reexamination and reconsideration of the application, as amended, are requested.

Rejections under 35 U.S.C. § 103(a) addressed

1. Claims 1-6, 9, 11-22 and 24-34 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Yu et al. (5,385,938) in view of Poli et al. (Food Chemistry), Wenniger (International Cosmetic Ingredient Dictionary), the Merck Index, and Pamukoff. This rejection is respectfully traversed.

Independent claim 1 as amended herein is directed to a method for treating an inflammation or lesion on a human or animal in need of said treatment, wherein said inflammation or lesion is caused by a virus, comprising contacting said inflammation or lesion with a virucidally effective amount of a composition consisting essentially of

a synergistic combination, said combination consisting of a C1, a C2, or a C3 alcohol or a C2, C3, or C4 diol having a concentration of 0.2 to 13.0% by volume in water, and a sufficient amount of an acid to adjust the pH of the synergistic combination to between 2.45 and 4.6.

It is well known that the transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps and those that do not materially affect the basic and novel characteristic(s) of the claimed invention. Accordingly, the transitional phrase "consisting essentially of" requires that the composition contains a synergistic composition as set forth in claim 1, but excludes active agents other than the synergistic combination of the alcohol and acid.

Further, the phrase "consisting of" in claim 1 clearly indicates that the synergistic combination contains only:

- a C1-C3 alcohol or a C2-C4 diol having a concentration of 0.2 to 13.0% by volume in water, and

- a sufficient amount of an acid to adjust the pH of the synergistic combination to between 2.45 and 4.6.

Accordingly, any element or ingredient other than a C1-C3 alcohol or a C2-C4 diol having a concentration of 0.2 to 13.0% by volume in water and a sufficient amount of an acid to adjust the pH of the synergistic combination to between 2.45 and 4.6 is excluded from the synergistic combination of claim 1. Independent claims 21 and 34 have been amended in a manner similar to that of claim 1 and therefore the above remarks apply equally to the amendments made to claims 21 and 34.

In contrast, Yu teaches a first example of composition containing two agents: an alpha hydroxyacid or alpha ketoacid and an amphoteric or pseudoamphoteric compound. The amphoteric or pseudoamphoteric compound is intentionally added to raise the pH of the composition in order to avoid skin irritation (see column 4, lines 2-12). Specifically, Yu states that a 1 molar aqueous solution of glycolic acid has a pH of 1.9, but the pH of the composition changes to 3.0 or 3.2 when an amphoteric compound such as arginine or creatinine, respectively, is combined with the glycolic acid solution. Thus, in this example Yu's active composition requires both an alpha hydroxyacid and an amphoteric compound. Therefore Yu's composition contains an element, i.e., an amphoteric compound, which is specifically excluded from the elements allowed in the synergistic combination of claims 1-6 and 9-33.

Yu also describes a formulation containing specific alpha hydroxy acids which are therapeutically effective for certain skin disorders without utilizing an amphoteric system (column 11, line 55-column 12, line 2), and provides glycolic acid as an example of an effective alpha hydroxy acid. However, as discussed above, the pH of a glycolic acid solution that does not include an amphoteric compound is 1.9, which is outside of the pH range of 2.45 to 4.6 as required in claim 1. Accordingly, this alternative composition disclosed by Yu is also outside of the scope of claims 1-6, 9-14, 16-23, and 25-26 as presently pending.

Therefore, since Yu does not teach or even suggest every element of the claims as presently pending, the claims are not obvious in light Yu alone or in combination with the other cited references.

The Examiner asserts that Yu does not expressly teach that the glycolic acid containing topical composition is useful in inactivating lesions caused by viruses within the Herpesviridae family, and relies on Poli for teaching that glycolic acid is virucidal against herpesvirus. Poli describes a study to determine the in vitro antiviral activity of certain organic acids. Poli found

that certain organic acids have antiviral activity, and that this activity was found to be proportional to the polarity of the molecule (page 255, last paragraph). However, it is asserted that Poli does not teach or even suggest that the pH of the acid solution is critical for virucidal activity. Further, Poli does not teach or even suggest a method for treating an inflammation or lesion caused by a virus comprising contacting the inflammation or lesion with a composition consisting essentially of a synergistic combination consisting of a low concentration of a lower chain alcohol and an acid at a specific pH. Thus, even if there were a motivation to combine the acids disclosed by Poli with the Yu composition, such a combination would not teach the methods of the present invention.

Next, the Examiner asserts that while Yu does not expressly teach that 1,3-butanediol is useful as a pharmaceutical vehicle, Wenniger teaches that 1,3-butanediol is useful as a solvent in numerous cosmetic marketed products. However, it is asserted that the Wenniger reference adds nothing to Yu that would render claims 1-6 and 9-14, 16-23 and 25-26 obvious. Even if there were a motivation to combine the references, the combination would not provide a method for treating an inflammation or lesion caused by a virus comprising contacting the inflammation or lesion with a composition **consisting essentially of** a synergistic combination, said synergistic combination consisting of a C1-C3 alcohol or a C2-C4 diol having a concentration of 0.2 to 13.0% by volume in water, and a sufficient amount of an acid to adjust the pH of the composition to between 2.45 and 4.6.

Next, the Examiner asserts that while Yu does not expressly teach the composition having a specific pH of 2.45 and does not teach the concentration of glycolic acid in the composition as 0.6%, the Merck Index teaches that the pH of a 0.5% glycolic acid is 2.50. However, it is asserted that the Examiner's inclusion of the Merck Index adds nothing to the above combination of references that would render claims 1-6 and 9-14, 16-23 and 25-26 obvious. As stated, the novel feature of the present invention is the synergistic combination **consisting of** a C1-C3 alcohol or a C2-C4 diol having a concentration of 0.2 to 13.0% by volume in water, and a sufficient amount of an acid to adjust the pH of the composition to between 2.45 and 4.6. That is, the inventors discovered that this novel synergistic combination can be used to treat an inflammation or lesion caused by a virus when applied topically to the inflammation or lesion. Thus, the Examiner's use of the Merck Index citation is weak at best and shows that the Examiner clearly is not considering the invention as a whole.

Finally, the Examiner asserts that Pamukoff teaches a composition containing 1-10% ethanol for treating viral infections broadly and in particular infections that are caused by Herpes

virus. However, contrary to the Examiner's assertion, Pamukoff did not provide evidence that ethanol alone provided a virucidal composition, but rather only demonstrated that ethanol was effective only when in combination with an alkali metal halide salt and glycerine. The "consisting essentially of" language of the present claims specifically excludes a metal salt and glycerine. Further, there is no suggestion in Pamukoff that the addition of an acid to his composition would provide a virucidal composition. Consequently, persons skilled in the art would not have been motivated or guided by Pamukoff to arrive at the methods of the claimed invention. Contrary to the Examiner's assertion, the art relied on provides no motivation to combine the teachings of Pamukoff with the teachings of the other references to arrive at the compositions of the present invention. Thus, there is no reason why one would add an acid to the Pamukoff composition. Further, since Pamukoff states that his composition is already effective, there is no suggestion or motivation to modify the compositions of Pamukoff by adding an acid as suggested by the Examiner. "Without some incentive or suggestion in the prior references to use materials disclosed in the referenced in the manner claimed by a patent applicant, a rejection of applicant's claimed invention is improper." *Ex parte* Shepard and Gushe, 188 USPQ 536 (PTO Bd. App. 1974); *In re* Samour, 197 USPQ 1 (CCPA 1978).

In summary, even if there were motivation to combine the above references, the combination still would not provide the novel methods of claims 1-6 and 9-33 as amended herein. Withdrawal of this rejection is respectfully requested.

2. Claims 1 and 7-8 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Bhatia et. al. (Indian J. Animal Sci.) and Pamukoff. The Examiner asserts that Bhatia teaches that 0.4N hydrochloric acid is effective in inactivating sheep pox virus, and Pamukoff teaches a 1-10% ethyl alcohol containing composition for treating viral infections broadly and in particular the infections that are caused by Herpes virus. The Examiner then concludes that although the references do not expressly teach the claimed virus-inactivating method employing both ethanol and HCl and further do not expressly teach a pH of 2.45 as used in the claimed method, it would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust the pH of the composition to 2.45. The Examiner's reasoning is that Bhatia separately teaches that acid inactivates viruses and Pamukoff separately teaches that alcohol is useful in activating viruses, and therefore it "flows logically to combine the two compositions which are known to be useful to treat viral lesions individually into a single composition useful for the very same purpose is prima facie obvious". This rejection is respectfully traversed.

First, presuming *arguendo* that the references show that the elements of the pending claims, the examiner has presented no line of reasoning as to why the one skilled in the art, viewing only the collective teachings of the cited references, would have found it obvious to selectively pick and choose various elements and/or concepts of the references relied on to arrive at the claimed invention. Rather, the Examiner has done little more than cite references to show that one or more elements, when each is in a vacuum, is known. The claimed invention, however, is clearly directed to a combination of elements. That is to say, the inventors do not claim that they have invented one or more new elements but have presented claims to a method of using a novel combination of elements. To support the conclusion that the claimed combination is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed combination, or the Examiner must present a convincing line of reasoning as to why persons skilled in the art would have found the claimed invention to have been obvious in light of the teachings of the references. It is noted that simplicity and hindsight are not proper criteria for resolving the issue of obviousness. Note *In re Horn*, 203 USPQ 969,971 (CCPA 1979).

Next, it is asserted that the references relied on do not teach the elements of the presently claimed invention. The purpose of Bhatia was to determine if hydrochloric acid would inactivate the goat-pox virus *in vitro* **prior** to contacting the acid with the goats' skin. Bhatia discloses a method of combining goat-pox virus with hydrochloric acid and incubating this suspension for a period of time (see page 518, second column, last paragraph). In order to determine if the virus was still active after incubation with acid, Bhatia injected the suspension under the goats' skin and watched for signs of pain at the injection site.

Thus, the Bhatia composition is actually a mixture of the goat-pox virus and a concentrated acid. Further, Bhatia only demonstrates that acid kills a virus *in vitro*. Bhatia does not teach or even suggest applying acid to the skin to treat an inflammation or lesion caused by a virus. More importantly, Bhatia does not teach or even suggest a method for treating an inflammation or lesion, comprising contacting said inflammation or lesion with a virucidally effective amount of a composition consisting essentially of a synergistic combination, said synergistic combination consisting of a C1, a C2, or a C3 alcohol or a C2, C3, or C4 diol having a concentration of 0.2 to 13.0% by volume in water, and a sufficient amount of an acid to adjust the pH of the synergistic combination to between 2.45 and 4.6.

Further, it is asserted that the combination of Bhatia and Pamukoff would not render the method of claims 1 and 7-8 obvious. As stated above, Pamukoff did not provide evidence that

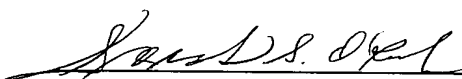
ethanol alone provided a virucidal composition, but rather only demonstrated that ethanol was effective only when in combination with an alkali metal halide salt and glycerine. The "consisting essentially of" language of the present claims specifically excludes a metal salt and glycerine. Further, there is no suggestion in Pamukoff that the addition of an acid to his composition would provide a virucidal composition. Consequently, persons skilled in the art would not have been motivated or guided by Pamukoff to arrive at the methods of the claimed invention. Accordingly, even if there were a motivation to combine the teachings of Bhatia with the teachings of Pamukoff, the combination would not render the methods of this invention obvious. Withdrawal of this rejection is respectfully requested.

CONCLUSIONS

All of the remarks in the final Office Action have been addressed, all claims now pending are believed to be in condition for allowance, and such action is respectfully requested. The fee for filing a Petition for a three month time extension is included with this response. Should any additional fees be due, the Examiner is authorized to charge any fee deficiency associated with this response to Deposit Account No. 50-1123. The Examiner is asked to kindly contact the undersigned by telephone should any outstanding issues remain.

Respectfully submitted,

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